

REMARKS

Claims 2, 57, 58, 63, 64, 68, 72, 75-96, 99-101, 103 and 112 are pending in the application.

Summary of Amendments

The Title of the Specification is amended to recite “Novel Pyrimidine Derivatives and Pharmaceutical Compositions Thereof.” Applicants respectfully submit that the above amendment obviates the Examiner’s objection to the Title of the specification.

Claims 2, 75, 82, 83 and 84 are amended to define the heterocyclyloxy and monocarbocyclic arylamino groups as pyridinyloxy or 1H-pyrazolyloxy and mono-phenylamino, respectively. Support for the definition of the heterocyclyloxy group can be found, for example, at Examples 2639 and 3356 of the specification. Support for the definitions of the monocarbocyclic arylamino group can be found, for example, at Examples 2635, 2941-948 and 3256 of the specification.

Claims 2, 75, 82 and 83 are further amended to delete the recitation of heterocyclylthio, heterocyclylsulfonyl and di-carbocyclic arylamino groups.

Claim 2 is still further amended to clearly recite that R₅ and R₁ together with the nitrogen atoms to which each is bonded forms a heterocyclyl group.

No new matter is added. Accordingly, Applicants respectfully request entry of the Amendment.

Response to Claim Rejections Under 35 U.S.C. § 112

- (i) **Claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner indicates that this is a new matter rejection.**

Specifically, the Examiner states that there is no support in the application as filed for the added limitations in claim 2 of the definitions of R₁, R₂, L, Y, and the added limitations to the definitions of carbocyclic aryl, carbocyclyl and heterocyclyl.

Applicants respectfully disagree with the Examiner. In the Amendment filed October 16, 2007, claim 1 was canceled and claim 2 was amended as follows to incorporate certain limitations that were present in claim 1:

The definition of R₁ was not changed from original claim 2.

The definitiona of Q was amended to be a pyrimidyl group, i.e., a compound of formula (IV).

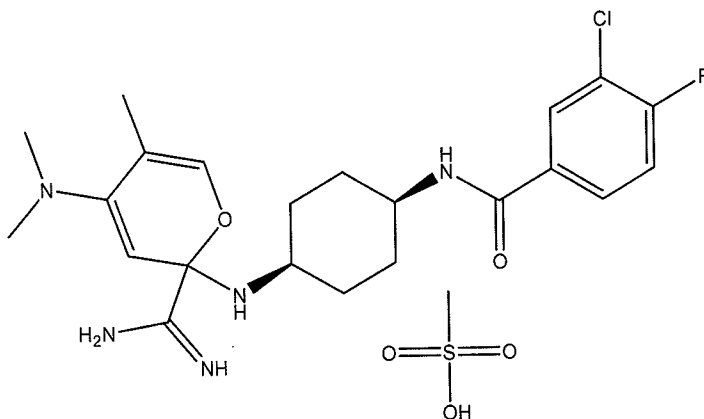
As Q could no longer be a compound of formula (II), the definition of R₂ was amended to remove that portion for when Q is a compound of formula (II), i.e., “or R₂ is methlyamino or dimethylamino when Q is Formula (II) and Y is a single bond or CH₂.” R₂ was also amended to delete one member of a Markush group, namely hydrogen.

The definition of L was amended to be a 1,4-cis-cyclohexyl compound of formula (VII).

The definition of Y was amended to recite the definition for when L is a compound of formula (VII).

Further, the definitions of the terms carbocyclyl aryl, carbocyclyl and heterocyclyl were present in original claim 2. Therefore, the only issue is whether there is written description support for a subgenus of compounds where L is a 1,4-cis-cyclohexyl compound of formula (VII).

In this respect, a majority of the working Examples, if not all, have the pyrimidinyl group attached to a 1,4-cis-cyclohexyl group. Additionally, in the Response to Election of Species Requirement filed March 13, 2007, Applicants elected the following compound:



, which includes a 1,4-cis-cyclohexyl group. Therefore, there is ample support within the working Examples of the present specification to choose L to be 1,4-cis-cyclohexyl from among the 16 compounds disclosed in original claim 1.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 112, first paragraph rejection of claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112.

- (ii) **Claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.**

Specifically, the Examiner asserts that the present specification does not sufficiently define the following terms of claim 2:

- **The terms "heterocycloxy", "heterocyclthio", "heterocyclsulfonyl" and other variants.**

Applicants submit that the deletion of the terms heterocyclthio and heterocyclsulfonyl, and the amendment to define the heterocycloxy group as pyridinyloxy or 1H-pyrazolyloxy, obviates the § 112, second paragraph rejection based on the above-

identified terms.

- **The phrases "mono-carbocyclic aryl amino substituted by ..." and "di-carbocyclic aryl amino substituted by ..."**

Applicants submit that the deletion of the phrase "di-carbocyclic aryl amino, and the amendment to define the mono-carbocyclic aryl amino as mono-phenylamino, obviates the § 112, second paragraph rejection based on the above-identified terms.

- **The difference between "cycloalkyl" and "carbocyclyl"**

Applicants submit that the term "carbocyclyl" is sufficiently defined in the present claims, for example, at the end of claim 2.

Applicants further submit that the term "cycloalkyl", as understood in the pertinent art, refers to a univalent radical derived from a cycloalkane by removal of a hydrogen atom, i.e., the cyclic structure is saturated and contains only carbon atoms.

In view of the above, Applicants respectfully submit that the terms "cycloalkyl" and "carbocyclyl" are well-defined.

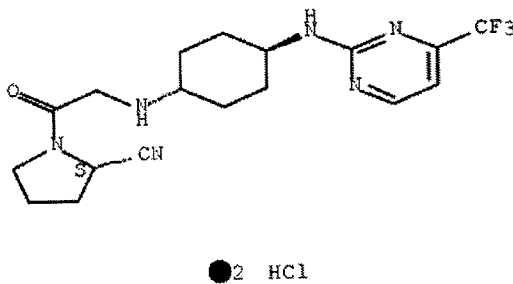
- **The phrase "R₅ and R₁ together with the nitrogen they are bonded [sic] form a heterocycl", because it is not grammatically correct in that it tends to indicate that R₅ and R₁ are bonded to the same nitrogen atom**

The amendment to claim 2 to recite R₅ and R₁ together with the nitrogen atoms to which each is bonded forms a heterocyclyl group, obviates the § 112, second paragraph rejection based on the above phrase.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the § 112, second paragraph rejection of claims 2, 75-79, 82-85, 88-90, 93, 94, 100, 103 and 112.

Response to Claim Rejections Under 35 U.S.C. § 103

- (i) **Claims 2, 75, 103 and 112 are rejected under 35 U.S.C. § 103(a) over Ackerman, et al. (U.S. Patent No. 7,012,077). Specifically, the Examiner asserts that Ackerman teaches the following compounds listed at pages 6-8 of the Office Action.**
- (ii) **Claims 2, 103 and 112 are also rejected under 35 USC § 103(a) over Yasuda, et al. (WO 2002030891). Specifically, the Examiner states that Yasuda describes the following dipeptidyl peptidase IV inhibitor:**



Applicants traverse the rejection for at least the following reason.

It is the Examiner's position that the presently claimed compounds are lower alkyl homologs or position isomers of the Ackermann and Yasuda compounds, and therefore obvious for the same utility.

Applicants note that all of the compounds of Ackermann and Yasuda that the Examiner relies on have a 1,4-trans-cyclohexyl structure. Further, Applicants have already provided experimental data in the Rule 132 Declaration by Kanuma Kosuke filed September 5, 2008 where the activity of compounds varying only in the presence of a 1,4-cis-cyclohexyl group and a 1,4-trans-cyclohexyl group were compared. The data shows that compounds having a 1,4-cis-cyclohexyl structure have remarkable antagonistic activity for the human MCH1 receptor, whereas compounds which do not have the 1,4-cis-cyclohexyl structure, i.e., compounds with a 1,4-trans-cyclohexyl structure, do not show any significant antagonistic activity. Therefore, the

experimental data in the Rule 132 Declaration shows that the presently claimed compounds have unexpectedly superior properties over the compounds of Ackermann and Yasuda.

Moreover, the compounds disclosed in Ackermann inhibit the enzyme activity of 2,3-oxidosqualene-lanosterol cyclase. See column 26, lines 17-64 of Ackerman. Furthermore, the compounds disclosed in Yasuda inhibit the enzyme activity of dipeptidyl peptidase IV. In contrast, the presently claimed compounds, which exhibit antagonist activity against MCH receptors, have entirely different properties when compared to compounds disclosed in Ackermann and Yasuda.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the § 103(a) rejections of claims 2, 75, 103 and 112, as being patentable over Ackermann and Yasuda.

Conclusion

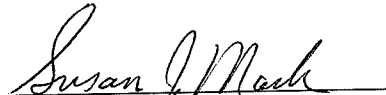
In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111
Application No.: 10/812,075

Attorney Docket No.: Q74855

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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Date: August 21, 2009